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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,186	09/29/2003	Rudolph Nobis	END5212USNP	2665
27777	7590	09/04/2008	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			KASZTEJNA, MATTHEW JOHN	
			ART UNIT	PAPER NUMBER
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			09/04/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/674,186

**Applicant(s)**

NOBIS ET AL.

**Examiner**

MATTHEW J. KASZTEJNA

**Art Unit**

3739

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-16 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-16 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Notice of Amendment***

In response to the amendment filed on May 22, 2008, amended claims 14, 16 and 22 and canceled claims 17-20 are acknowledged. The following new and reiterated grounds of rejection are set forth:

### ***Claim Objections***

Claim 14 is objected to because of the following informalities: the word "*and* each of the proximal and distal ends..." appears to be a typo, in line 4 of the claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-11 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,643,653 to Takahashi et al.

**In regards to claim 10**, Takahashi et al. disclose a medical device comprising: a flexible member 14; an end effector 34 operatively associated with a distal end of the flexible member; and a handle 12 operatively associated with the proximal end of the flexible member; wherein the handle comprises an actuator 36 for operating the end effector through the flexible member (see Col. 5, Lines 65-75), wherein the proximal end of the flexible member is fixed relative to the handle, and wherein the flexible member

extends from a single end of the handle (see Fig. 12); and wherein an outer surface of the handle is sized and shaped to be gripped by a single hand and wherein the actuator is disposed on the handle. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

**In regards to claim 11**, Takahashi et al. disclose a medical device wherein the end effector is selected from the group consisting of a biopsy forceps, grasping forceps, surgical scissors, extractors, washing pipes, needle injectors, non energized snares, and electrosurgical snares (see Col. 6, Lines 1-40).

**In regards to claim 14**, Takahashi et al. disclose a medical device wherein the handle has a proximal end, a distal end, and an outer surface, the handle outer surface having a maximum width dimension disposed intermediate the proximal and distal ends of the handle (see Fig. 18). As seen in Figure 18, the outer surface has a relatively smaller width dimension at each of the proximal and distal ends of the handle, as the eye piece is interpreted as being part of the handle as it is capable of being held and part of the handle.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,643,653 to Takahashi et al. in view of U.S. Patent No. 5,624,379 to Ganz et al.

**In regards to claims 12-13,** Takahashi et al. disclose a medical device comprising: a flexible member 14 and an end effector operatively associated with a distal end of the flexible member but are silent with respect to wherein the flexible member is at least one meter long. Ganz et al. teach of an analogous endoscopic instrument wherein the flexible member is at least one meter long. Moreover the length of the elongate member may vary according to its intended application (see Col. 3, Lines 30-35). It would have been obvious to one skilled in the art at the time the invention was made to construct a flexible member in the apparatus of Takahashi et al. of a length of at least one meter long to provide access to a variety of desired treatment sites deep within body lumen as taught by Ganz et al. and is well-known in the art.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,643,653 to Takahashi et al. in view of U.S. Patent No. 6,533,797 to Stone et al.

**In regards to claim 15,** Takahashi et al. disclose a medical device comprising: a flexible member 14 and an end effector operatively associated with a distal end of the flexible member but are silent with respect to wherein the actuator comprises a lever. Stone et al. teach of an analogous medical device wherein the actuator is a lever mechanism adapted to be squeezed and pivotably supported on an end of the handle (see Figs. 3-5). Thus Stone et al. demonstrate that the use of levers as actuators was

well known in the art at the time the invention was made. It would have been obvious to one skilled in the art at the time the invention was made to use a lever actuator in the apparatus of Takahashi et al. to provide an alternate actuator providing greater comfort and maneuverability to the user as taught by Stone et al.

Claims 16 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,643,653 to Takahashi et al. in view of U.S. Patent No. 6,620,184 to de Laforcade et al.

**In regards to claims 16 and 22-26,** Takahashi et al. disclose a medical device comprising: an end effector 17 having a first and a second configuration (i.e. lens barrel moved proximally or distally); handle 12; a flexible shaft 5 extending intermediate the end effector and the handle; the handle comprising: a housing adapted to be grasped by a single hand' an actuator associated with the housing and operable by the hand holding the housing to actuate the end effector from the first configuration to the second configuration; wherein at least the thumb and index finger of the same hand holding the housing are free to grip and release the flexible shaft of the device (see Figs. 3 and 12, Col. 4, Lines, 1-10 and Col. 6, Lines 1-10). The words "for" and "adapted to" in the claims may be properly interpreted as "capable of," and "capable of" does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d

1647 (1987). Takahashi et al. also teach of forceps 42a (see Fig. 18) inserted through a working channel of the endoscope but are silent with respect to the specific control members of the forceps. The forceps may alternatively be interpreted as the end effector operable between first and second configurations. Takahashi et al. are silent with respect to a specific control member for actuating the forceps and more specifically with respect to a release operable for returning the end effector to the first configuration. De Laforcade et al. teach of an analogous apparatus having a ratchet release mechanism for a medical device. The release mechanism permits both a smooth and a stepped actuation of a grasper on a distal end of the medical device. The medical device has a fixed handle and a movable handle. The release mechanism comprises an elongated toothed plate arrangement supported in a release housing and an elongated smooth plate arranged adjacent the toothed plate arrangement in the release housing. The release housing is pivotably supported between the handles to permit the handles to move in a stepped or a smooth manner to effect actuation of the grasper (see Figs. 1 and 2). It would have been obvious to one skilled in the art at the time the invention was made to include a release mechanism in the apparatus of Takahashi et al. to provide an actuator that is simple to operate and inexpensive to manufacture and to provide a release mechanism which permits that medical grasper device to be multi-functional, to maintain and/or to immediately release a grasping or treatment configuration to that medical device as taught by de Laforcade et al.

***Response to Arguments***

Applicant's arguments filed May 22, 2008 have been fully considered but they are not persuasive.

In response to applicant's argument that Takahashi et al. fail to teach an apparatus adapted for use with one hand, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Furthermore, the apparatus of Takahashi et al. as seen in Figure 12, is fully *capable* of being gripped with one hand wherein the palm is placed upon the bottom of the handle and the middle finger is capable of being used to operate actuator 36. This would then leave both the thumb and index free for grasping flexible tube 14. Flexible tube 14 is long enough and flexible enough to be bent backwards to be grasped by the operators index finger and thumb. Lacking further structural limitations (i.e. swivel ring 55 as seen in Figure 3 of the instant invention), Takahashi et al. meet the current limitations of the instant invention as broadly as claimed.

Applicant's arguments with respect to claims 16 and 22-26 have been considered but are moot in view of the new ground(s) of rejection.



***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MATTHEW J. KASZTEJNA** whose telephone number is (571)272-6086. The examiner can normally be reached on **Mon-Fri, 8:30-6:00**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./  
Examiner, Art Unit 3739

/Linda C Dvorak/  
Supervisory Patent Examiner, Art  
Unit 3739

8/19/8